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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807 92

The assigned 510(k) number is _____

1. **Manufacturer and Sponsor Contact Information**

JAN 21 2009

1 1 Manufacturer
JMS Singapore Pte Ltd
440 Ang Mo Kio Industrial Park 1
Singapore 569620

1 2 Sponsor
JMS North America Corporation
22320 Foothill Blvd , Suite 350
Hayward, CA 94541
USA

1 3 Contact Information
Yvonne Lim
QA Specialist
JMS North America Corporation
22320 Foothill Blvd, Suite 350
Hayward, CA 94541
Telephone (510) 888-9090
Fax (510) 888-9099

Date Summary Prepared September 29, 2008

2 **Name of the Device:** JMS AV Fistula Blunt Needle Set
Classification name: 21 CFR 876 5540
Product Code FIE

3. **Common or Usual Name**
AV Fistula Blunt Needle Set

4. **Predicate Device Information:**
The predicate device used in this submission is
1) Medisystems Buttonhole Needle Sets (K990803),
2) JMS AV Fistula Needle Set WingEater (K010406)
3) JMS Sysloc Mini AVF and Apheresis Needle Set (K070234)

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5 **Device Description:**
JMS AV Fistula Blunt Needle Set is intended as a non-implanted blood access device, which consists of a needle that is attached to wings, a flexible tube and a luer lock connector

6. **Intended Use.**
The JMS Blunt AV Fistula Needle Set is intended for temporary cannulation (non-implantable, less than 30 days) to vascular access for extracorporeal blood treatment The device is intended for single use only The JMS AV Fistula Blunt Needle Set is for use on developed 'constant site' access sites

7. **Comparison to Predicate Devices:**
The predicate device used in this submission is Medisystems Buttonhole Needle Sets (K990803) in terms of indications of use and performance characteristics In terms of material, the predicate device is JMS AV Fistula Needle Set WingEater (K010406) and JMS Sysloc Mini AVF and Apheresis Needle Set (K070234)

8. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence and Discussion of Clinical Tests Performed are as follows:**
Functional tests performance data are comparable to predicate device JMS A V Fistula Blunt Needle Set has the same intended usage, same materials used in the blood-contact components, and adopts identical fundamental scientific technology as the predicate devices Bench testing was conducted to verify that the JMS AV Fistula Blunt Needle Set performs as intended to be a safe and effective medical device, data and reports are enclosed within this submission document

9 **Conclusions**
The information provided in this submission clearly demonstrates the substantial equivalence of JMS AV Fistula Blunt Needle Set to the predicate device Medisystems Buttonhole Needle Sets (K990803) and JMS AV Fistula Needle Set WingEater (K010406) and JMS Sysloc Mini AVF and Apheresis Needle Set (K070234)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2009

JMS North America Corporation
c/o Ms Maria Griffin
Official Correspondent
MDI Consultants, Inc
55 Northern Blvd , Suite 200
GREAT NECK NY 11021

Re K082882
Trade/Device Name JMS A V Fistula Blunt Needle Set
Regulation Number 21 CFR §876 5540
Regulation Name Blood access device and accessories
Regulatory Class II
Product Code FIE
Dated December 30, 2008
Received December 31, 2008

Dear Ms Griffin

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801, good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter

21 CFR 876 xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884 xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry suppot/index html

Sincerely yours,

Janine M Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known) _____

Device Name JMS A V Fistula Blunt Needle Set

Indications For Use

The JMS Blunt AV Fistula Needle Set is intended for temporary cannulation (non-implantable, less than 30 days) to vascular access for extracorporeal blood treatment The device is intended for single use only The JMS AV Fistula Blunt Needle Set is for use on developed 'constant site' access sites

Prescription Use __X___ **Over-The Counter Use**_____
(Per 21 CFR 801 Subpart D) **OR** **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal
Radiological Devices
510(k) Number K082882